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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC., Plaintiffs, v. CIPLA LIMITED and CIPLA USA INC., Defendants.	Civil Action No. _____ **COMPLAINT FOR PATENT INFRINGEMENT AND CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 11.2**

Plaintiffs AstraZeneca AB, Aktiebolaget Hassle, AstraZeneca LP, and Zeneca Inc. (collectively, "Plaintiffs"), by their attorneys, for their Complaint against Defendant Cipla Limited and Cipla USA Inc. (collectively, "Defendants" or "Cipla"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., and in particular under 35 U.S.C. § 271(e). This action relates to Abbreviated New Drug Application ("ANDA") No. 209542 filed by or for the benefit of Defendants with the United States Food and Drug Administration ("FDA") for approval to market generic versions of Plaintiffs' NEXIUM 24HR® pharmaceutical products that are sold in the United States.

THE PARTIES

2. Plaintiff AstraZeneca AB ("AZ AB") is a corporation operating and existing under the laws of Sweden, with its principal place of business at S-151 85 Södertälje, Sweden.

3. Plaintiff Aktiebolaget Hässle ("Hässle") is a corporation organized and existing under the laws of Sweden, having its principal place of business at Mölndal, Sweden.

4. Plaintiff AstraZeneca LP ("AZ LP") is a limited partnership operating and existing under the laws of the State of Delaware, with its principal place of business at 1800 Concord Pike, Wilmington, Delaware 19803. AZ LP holds an approved New Drug Application from the FDA for an esomeprazole magnesium formulation that it sells under the name NEXIUM 24HR®.

5. Plaintiff Zeneca Inc. ("Zeneca") is a Delaware corporation having its principal place of business at Wilmington, Delaware. Zeneca has exclusive rights in the United States to market and sell products covered by United States Patent Nos. 6,369,085 and 7,411,070 (collectively, the "Patents-in-suit").

6. On information and belief, Defendant Cipla Limited ("Cipla Ltd.") is a corporation operating and existing under the laws of India, with its principal place of business at

Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, India.

7. On information and belief, Defendant Cipla USA Inc. ("Cipla USA") is a corporation operating and existing under the laws of the State of Delaware, with its principal place of business at 9100 S. Dadeland Blvd., Suite 1500, Miami, FL 33156.

8. On information and belief, Cipla USA is a wholly-owned subsidiary of Cipla Ltd.

BACKGROUND

The NDA

9. AZ LP is the holder of New Drug Application ("NDA") No. 207920 for NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Tablets, 20 mg. NEXIUM 24HR® is an over-the-counter drug approved for the treatment of frequent heartburn (2 or more days a week). Esomeprazole magnesium trihydrate is the active ingredient in NEXIUM 24HR®.

The Patents-in-Suit

10. United States Patent No. 6,369,085 ("the '085 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the United States Patent and Trademark Office ("the USPTO") on April 9, 2002 to AZ AB, upon assignment from the inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Möller. The '085 patent claims, *inter alia*, magnesium salts of esomeprazole trihydrate, pharmaceutical compositions comprising the claimed salts, methods of treatment using the claimed salts, and processes for preparing the claimed salts. A true and correct copy of the '085 patent is attached as Exhibit A.

11. Plaintiff AZ AB has been and still is the owner of the '085 patent. The '085 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '085 patent expires on November 25, 2018.

12. United States Patent No. 7,411,070 ("the '070 patent"), entitled "Form of S-omeprazole," was duly and legally issued by the USPTO on August 12, 2008 to AZ AB upon assignment from inventors Hanna Cotton, Anders Kronstrom, Anders Mattson, and Eva Moller. The claims of the '070 patent are directed to, *inter alia*, magnesium salts of esomeprazole trihydrate and processes for preparing the claimed salts. A true and correct copy of the '070 patent is attached as Exhibit B.

13. Plaintiff AZ AB has been and still is the owner of the '070 patent. The '070 patent will expire on May 25, 2018, and pediatric exclusivity relating to the '070 patent expires on November 25, 2018.

The ANDA

14. On information and belief, Cipla filed ANDA No. 209542 with the FDA under 21 U.S.C. § 355(j) to obtain FDA approval for the commercial manufacture, use, importation, offer for sale, and sale in the United States of esomeprazole magnesium delayed-release tablets, 20 mg (OTC) ("Cipla's ANDA Product"), which are generic versions of Plaintiffs' NEXIUM 24HR® Esomeprazole Magnesium Delayed-Release Tablets, in a 20 mg dosage form.

15. By letter dated November 15, 2016 (the "ANDA Notice Letter"), Defendants notified Plaintiffs that they had filed ANDA No. 209542 seeking approval to market Cipla's ANDA Product and that Cipla was providing information to Plaintiffs pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95.

JURISDICTION AND VENUE

16. Subject matter jurisdiction over this action is proper pursuant to the provisions of Title 28, United States Code, Sections 1331 and 1338(a).

17. On information and belief, Cipla Ltd. is a corporation operating and existing under the laws of India, with its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai-400013, India.

18. On information and belief, Cipla Ltd., either directly or through one or more of its wholly-owned subsidiaries and/or agents, develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

19. On information and belief, Cipla USA is a corporation operating and existing under the laws of Delaware, with its principal place of business in Florida.

20. On information and belief, Cipla USA, with the assistance and/or at the direction of Cipla Ltd., develops, manufactures, distributes, markets, offers to sell, and sells generic drug products for sale and use throughout the United States, including within this judicial district.

21. On information and belief, Defendants acted in concert to develop Cipla's ANDA Product and to seek approval from the FDA to sell Cipla's ANDA Product throughout the United States, including within this judicial district.

22. On information and belief, both Cipla Ltd. and Cipla USA participated in the preparation and/or filing of ANDA No. 209542.

23. On information and belief and as stated in the ANDA Notice Letter, the FDA received ANDA No. 209542 from Cipla Ltd.

24. On information and belief, by virtue of, *inter alia*, the sales-related activities of Defendants in New Jersey, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of pharmaceutical products to residents of New Jersey, this Court has personal jurisdiction over Defendants.

25. On information and belief, Defendants have previously been sued in this district and have consented to personal jurisdiction in those actions. *See, e.g.*, *Janssen Prods., L.P. et al. v. Cipla Ltd. et al.*, Civil Action No. 2:14-cv-05093-WHW-CLW (D.N.J.), Answer to Complaint, ¶ 13 (Sept. 10, 2014); *Merck, Sharp & Dohme Corp. et al. v. Cipla Ltd. et al.*, Civil Action No. 3:13-cv-04017 (JBS) (AMD) (D.N.J.), Answer to Complaint, ¶¶ 8-9 (November 22, 2013).

26. On information and belief, by virtue of, *inter alia*, Defendants' continuous and systematic contacts with New Jersey, including but not limited to the above-described contacts, and the actions on behalf of Defendants in connection with ANDA No. 209542, this Court has personal jurisdiction over Defendants. These activities satisfy due process and confer personal jurisdiction over Defendants consistent with New Jersey law. *See, e.g.*, *Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755, 762-63 (Fed. Cir. 2016) (holding that minimum-contacts requirement for specific personal jurisdiction is established where Defendant's "ANDA filings and its distribution channels establish that [the Defendant] plans to market its proposed drugs in [the State where the complaint was filed] and the lawsuit is about patent constraints on such in-State marketing.").

27. Upon information and belief, Defendants intend to market Cipla's ANDA Product in New Jersey upon receiving FDA approval for ANDA No. 209542.

28. Venue is proper in this District pursuant to the provisions of Title 28, United States Code, Sections 1391(b)-(d), and 1400(b).

COUNT 1: INFRINGEMENT OF THE '085 PATENT

29. Plaintiffs incorporate by reference paragraphs 1-28 of this Complaint as if fully set forth herein.

30. On information and belief, Defendants submitted ANDA No. 209542 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Cipla's ANDA Product in the United States before the expiration of the '085 patent.

31. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '085 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product.

32. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 209542 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product before the expiration of the '085 patent constitutes infringement of one or more claims of the '085 patent, either literally or under the doctrine of equivalents.

33. On information and belief, Cipla's ANDA Product, if approved by the FDA, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '085 patent.

34. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

COUNT 2: INFRINGEMENT OF THE '070 PATENT

35. Plaintiffs incorporate by reference paragraphs 1-34 of this Complaint as if fully set forth herein.

36. On information and belief, Defendants submitted ANDA No. 209542 to the FDA under 21 U.S.C. § 355(j) in order to obtain approval to market Cipla's ANDA Product in the United States before the expiration of the '070 patent.

37. By their ANDA Notice Letter, Defendants informed Plaintiffs that they had submitted to the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the '070 patent is invalid, unenforceable, or will not be infringed by the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product.

38. Under 35 U.S.C. § 271(e)(2)(A), the submission by Defendants to the FDA of ANDA No. 209542 to obtain approval for the commercial manufacture, use, sale, offer for sale, or importation into the United States of Cipla's ANDA Product before the expiration of the '070 patent constitutes infringement of one or more claims of the '070 patent, either literally or under the doctrine of equivalents.

39. On information and belief, Cipla's ANDA Product, if approved by the FDA, will be administered to human patients in a therapeutically effective amount to inhibit gastric acid secretion and for the treatment of gastrointestinal inflammatory disease. On information and belief, this administration will occur at Defendants' active behest and with their intent, knowledge, and encouragement. On information and belief, Defendants will actively encourage, aid and abet this administration with knowledge that it is in contravention of Plaintiffs' rights under the '070 patent.

40. Plaintiffs will be substantially and irreparably harmed by the infringing activities described above unless those activities are precluded by this Court. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '085 and '070 patents are valid and enforceable;

B. A judgment that the submission of ANDA No. 209542 by Defendant infringes one or more claims of each of the '085 and '070 patents under 35 U.S.C. § 271(e)(2);

C. A judgment providing that, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any FDA approval of Defendant's ANDA No. 209542 shall be no earlier than the latest expiration date of the Patents-in-suit and any additional periods of exclusivity;

D. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant, and all persons acting in concert with Defendant, from making, using, selling, offering to sell, or importing the esomeprazole magnesium product described in Defendant's ANDA No. 209542 prior to the latest expiration of the Patents-in-suit and any additional periods of exclusivity;

E. Attorneys' fees in this action pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Such further and other relief as this Court may deem just and proper.

Dated: December 29, 2016

Respectfully submitted,

s/ John E. Flaherty
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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter of the following actions:

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. WOCKHARDT LIMITED and WOCKHARDT USA LLC*, C.A. No. 3:13-cv-04854-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. No. 3:14-cv-4782-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ANDRX LABS, LLC, ANDRX CORPORATION, and ACTAVIS, INC.*, C.A. No. 3:14-cv-8030-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. PERRIGO COMPANY PLC, PERRIGO COMPANY, L. PERRIGO COMPANY, and PADDOCK LABORATORIES, LLC*, C.A. No. 3:15-cv-1057-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. HEC PHARM CO., LTD., HEC PHARM GROUP, and HEC PHARM USA INC.*, C.A. No. 3:15-cv-06025-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. LUPIN LTD. and LUPIN PHARMACEUTICALS INC.,*, C.A. No. 3:15-cv-06092-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. ZYDUS PHARMACEUTICALS (USA) INC., and CADILA HEALTHCARE LTD. (dba ZYDUS CADILA)*, C.A. 3:15-cv-07415-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC.*, C.A. No. 3:15-cv-08267-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. MACLEODS PHARMACEUTICAL LTD. and MACLEODS PHARMA USA, INC.*, C.A. No. 3:16-cv-01682-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. HETERO USA INC., HETERO LABS LIMITED UNIT-III, and HETERO LABS LIMITED*, C.A. No. 3:16-cv-02442-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. AUROBINDO PHARMA LIMITED and AUROBINDO PHARMA USA INC.*, C.A. No. 3:16-cv-04414-MLC-TJB (District of New Jersey)

- *ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, and ZENECA INC. v. GLENMARK PHARMACEUTICALS LTD., GLENMARK PHARMACEUTICALS SA, and GLENMARK PHARMACEUTICALS INC. USA*, C.A. No. 3:16-cv-07330-MLC-TJB (District of New Jersey)

Dated: December 29, 2016

Respectfully submitted,

s/ John E. Flaherty
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